IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of

OSTERHOFF et al.

Atty. Ref.: 35-196

Continuation of Serial No. 09/041,745

Group: 1646

Filed: Herewith

Examiner: ULM, J.D.

For: EPIDIDYMIS-SPECIFIC RECEPTOR PROTEIN

* * * * * * * * * * * *

December 8, 2000

Assistant Commissioner for Patents
Washington, DC 20231

PRELIMINARY AMENDMENT

Sir:

Preliminarily amend the above-identified application as follows.

IN THE CLAIMS:

Amend the claims as follows.

1. (Amended) An isolated mammalian epididymis-specific receptor protein which has the amino acid sequence shown [the] in SEQ ID NO: 2, or a derivative of said protein or a fragment of said protein, said derivative or fragment [thereof] having at least one biological activity and/or immunogenicity of said protein, wherein said derivative or fragment comprises at least ten contiguous amino acids of SEQ ID NO: 2.

2. (Amended) A protein of claim 1 wherein said derivative or fragment [is] comprises a hydrophilic region of said receptor.

3. (Amended) A protein of claim 2 wherein said derivative or fragment [is] comprises an extracellular hydrophilic region of said receptor.

4. (Amended) [A] An isolated protein [of claim 1] having a sequence selected from the group consisting of [represented by SEQ ID NO] SEQ ID NOs: 2, 3, 4, 5, 6 and 7.

5. (Amended) A protein of claim 1 herein said derivative or fragment [is] comprises at least one sequence selected from the group consisting of any one of SEQ ID NO: 3-7.

17. (Amended) A [pharmaceutical] composition which comprises a protein, derivative or fragment according to claim 1 [as an active component].

21. (Amended) A [pharmaceutical]composition [according to claim 17 for diagnosis of male reproduction disorders] comprising a protein according to claim 4.

23. (Amended) A method of isolating a ligand specific for an epididymis-specific receptor comprising incubating the epididymis-specific receptor protein of claim 1 with a substance suspected to be a ligand of said receptor and detecting binding of said receptor to said ligand.

26. (Amended) A method of treating infertility in a male mammal comprising administering an agonist of an epididymis-specific receptor protein of claim 1 to said made mammal.

27. (Amended) A contraceptive method for male mammals comprising administering an antagonist of an epididymis-specific receptor to said male mammal wherein said antagonist comprises a protein, derivative or fragment of claim 1.

30. (Amended) A method of diagnosing infertility in a male comprising measuring from said male to an epididymis-specific receptor protein of claim 1.

REMARKS

Reconsideration is requested.

Claims 1-30 are pending. The Examiner is requested to contact the undersigned in the event the Examiner believes the claims are directed to separately patentable subject matter.

With regard to the Section 101 rejection of claims 1-5, 17, 21, 31-38 and 48-51 stated in the June 9, 2000 Office Action of the parent application, the Examiner is requested to consider the following and the attached.

The Examiner's reliance on Brenner v. Manson 148 USPQ 689 (S Ct 1966) is misplaced as the Patent Office has previously acknowledged that Brenner dealt with the rare situation where

"an applicant fails entirely to indicate why the claimed invention is useful." See, fn, 4, page 16 of "Legal Analysis Supporting Utility Examination Guidelines", Department of Commerce, Patent and Trademark Office, Docket No. 950706162-5172-01 executed July 3, 1995, by Bruce A. Lehman, Assistant Secretary of Commerce and Commissioner of Patents and Trademarks (copy attached). The Patent Office has recognized that Brenner required an applicant to disclose a utility in his application. Specifically, the Patent Office has noted

> "Courts have found an application deficient under the "usefulness" portion of § 101 where the applicant has not identified any "specific" utility for the invention. Such situations arise rarely; namely where an applicant fails entirely to indicate why the claimed invention is useful. For example, in Brenner v. Manson, 383 U.S. 519, 148 USPQ 689 (1966), the Supreme Court affirmed a finding by the Office that a method of producing a particular class of steroids was deficient under § 101 because the applicant did not explain why the compounds produced by the claimed process were useful. The process in question was patented by another who had disclosed a utility for the invention. The Court refused to consider sufficient a general assertion, not made in the application as filed but instead made by the applicant during an interference proceeding, that the compounds in question were structurally similar to others and therefore might possess a particular biological activity in common with those other compounds. Thus, the Court focused on the fact that the applicant failed to identify any "specific utility" for the claimed invention in his application. A more recent case involved an assertion that a disclosure that a substance was "plastic-like" and could be pressed into films was insufficient to satisfy § 101. In re Ziegler, 992 F.2d 1197, 26 USPQ2d 1600 (Fed. Cir. 1993). As the court stated:
>
> > Ziegler did not assert any practical use for the polypropylene or its film, and Ziegler did not disclose any characteristics of the polypropylene or its film that demonstrated its utility. Ziegler did not even assert that the polypropylene was useful in applications where any of the solid

> plastics were used. Rather, Ziegler said the polypropylene was "plastic-like."

Id. at 1203, 26 USPQ2d at 1605. Thus, the failure of the applicant to either identify any use for the invention or to disclose features of the invention that would make uses of it readily apparent, was found to render the claimed invention deficient under § 101." Id.

Moreover, the Patent Office has appreciated that

> "Practical considerations require the Office to rely on the inventor's understanding of his or her invention in determining whether and in what regard an invention is believed to be "useful"...
> Courts have repeatedly found that the mere identification of a pharmacological activity of a compound that is relevant to an asserted pharmacological use provides an "immediate benefit to the public" and thus satisfies the utility requirement. As the CCPA held in Nelson v. Bowler:
>
> > Knowledge of the pharmacological activity of any compound is obviously beneficial to the public. It is inherently faster and easier to combat illnesses and alleviate symptoms when the medical profession is armed with an arsenal of chemicals having known pharmacological activities. Since it is crucial to provide researchers with an incentive to disclose pharmacological activities in as many compounds as possible, we conclude that adequate proof of any such activity constitutes a showing of practical utility. [206 USPQ at 883.]
>
> Similarly, courts have found utility for therapeutic inventions despite the fact that an applicant is at a very early stage in the development of a pharmaceutical product or therapeutic regimen based on a claimed pharmacological or bioactive compound or composition. Accordingly, Office personal should not construe § 101, under the logic of "practical" utility or otherwise, to require that an applicant demonstrate that a therapeutic agent based on a claimed invention is a safe or fully effective drug for humans.

> These general principles are equally applicable to situations where an applicant has claimed a process for treating a human or animal disorder. In such cases, the asserted utility is usually clear--the invention is asserted to be useful in treating the particular disorder. If the asserted utility is credible, there is no basis to challenge such a claim on the basis that it lacks utility under § 101." [Footnote references omitted.] Id, at pp. 4-5.

The footnotes of the Patent Office's Legal Analysis are instructive in providing a summary of the courts' requirements and are reproduced in the following for the Examiner convenience.

> "[23] The utility being asserted in Nelson related to the a compound with "pharmacological" utility. Nelson, 626 F.2d at 856, 206 USPQ at 883. Office personal should rely on Nelson and other cased as providing general guidance when evaluating the utility of an invention that is based on any therapeutic, prophylactic, or pharmacological activities of that invention.
>
> In Nelson v. Bowler, the CCPA addressed the practical utility requirement in the context of an interference proceeding. Bowler challenged the patentability of the invention claimed by Nelson on the basis that Nelson had failed to sufficiently and persuasively disclose in his application a practical utility for the invention. Nelson had developed and claimed a class of synthetic prostaglandins modeled on naturally occurring prostaglandins. Naturally occurring prostaglandins are bioactive compounds that, at the time of Nelson's application, had a recognized value in pharmacology (e.g., the stimulation of uterine smooth muscle which resulted in labor induction or abortion, the ability to raise or lower blood pressure, etc.). To support the utility he identified in his disclosure, Nelson included in his application the results of tests demonstrating the bioactivity of his new substituted prostaglandins relative to the bioactivity of naturally occurring protaglandins. The Court concluded that Nelson had satisfied the practical utility requirement in identifying the synthetic prostaglandins as pharmacologically active compounds. In reaching this conclusion, the court

> considered and rejected arguments advanced by Bowler that attacked the evidentiary basis for Nelson's assertions that the compounds were pharmacologically active.
>
> In In re Jolles, 628 F.2d 1322, 206 USPQ 885 (CCPA 1980), an inventor claimed protection for pharmaceutical compounds for treating leukemia. The active ingredient in the compositions was a structural analog to a known anti-cancer agent. The applicant provided evidence showing that the claimed analogs had the same general pharmaceutical activity as the known anti-cancer agents. The Court reversed the Board's finding that the asserted pharmaceutical utility was "incredible," pointing to the evidence that showed the relevant pharmacological activity.
>
> In Cross v. Iizuka, 753 F.2d 1040, 224 USPQ 739 (Fed. Cir. 1985), the Federal Circuit affirmed a finding by the Board of Patent Appeals and Interferences that a pharmacological utility had been disclosed in the application of one party to an interference proceeding. The invention that was the subject of the interference count was a chemical compound used for treating blood disorders. Cross had challenged the evidence in Iizuka's specification that supported the claimed utility. However, the Federal Circuit relied extensively on Nelson v. Bowler in finding that Iizuka's application had sufficiently disclosed a pharmacological utility for the compounds. It distinguished the case from cases where only a generalized "nebulous" expression, such as "biological properties," had been disclosed in a specification. Such statements, the court held, "convey little explicit indication regarding the utility of a compound," 753 F.2d at 1048, 224 USPQ 745 (citing In re Kirk, 376, F.2d 936, 941, 153 USPQ 48, 52 (CCPA 1967))."

The applicants note that the present application describes a number of useful products of the disclosed invention, as required by the courts. The comments noted by the Examiner in the applicants' publication (DNA and Cell Biol 16(4) 379-389 Apr 1997) are not evidence of a lack of a disclosed utility of the present application. The Examiner must appreciate that the cited publication discloses a utility while appreciating that further work, such as a reasonable amount of experimentation, may always be required or even "essential." Moreover, reference to passages

in the applicants' journal article fail to enlighten the analysis of the present disclosure, which describes a number of practical utilities for the disclosed and claimed invention. Accordingly, the Section 101 rejection of claims 1-5, 17, 21, 31-38 and 48-51 was inappropriate.

The Examiner is requested to see the attached Legal Analysis, specifically at pages 4-5 as well as the footnotes cited therein with regard to the Section 112, first paragraph rejection stated in the June 9, 2000, Office Action issued in the parent application.

An early and favorable Action is requested.

Respectfully submitted,

NIXON & VANDERHYE P.C.

By: ______________________
B.J. Sadoff
Reg. No. 36,663

BJS:rdw
1100 North Glebe Road, 8th Floor
Arlington, VA 22201-4714
Telephone: (703) 816-4091
Facsimile: (703) 816-4100